# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## The effectiveness of intra-articular Triamcinolone injection compared to 940nm diod laser therapy in the treatment of temporomandibular joint disorder (TMD) signs.

## Protocol summary

**Study aim**
Comparison the efficacy of intra-articular triamcinolone injection and laser treatment onImproving the Symptoms of Temporomandibular Joint Disorders(TMD)

**Design**
Patients are randomly divided into two 33-member group. Random allocation will be done through block randomization method.

**Settings and conduct**
Patient with TMD referring to facial and maxillofacial surgery centers in Hamedan

**Participants/Inclusion and exclusion criteria**
Inclusion Criteria was Patients with symptoms of TMD including pain; joint sound; limitation of mouth opening and jawbone deviation during opening mouth through clinical examinations and Exclusion Criteria was Age younger than 20 or older than 40; History of any surgery or intervention in the TMJ joint; History of connective tissue or joints disease such as lupus; scleroderma; vasculitis and etc; History of long-term use of corticosteroids and anti-inflammatory drugs.

**Intervention groups**
Intervention group 1: Treatment included cleaning the skin of the injection area with alcoholic pad and injecting 1 ml of Lidocaine 2% to desensitize the area, asking the patient to open his mouth to the maximum possible size and injecting 0.5 ml of triamcinolone into posterior disk space. Needle gage 27was used for injection.
Intervention group: 940 nm diode laser was used to radiate point by point at the head of condyle from superior, inferior, anterior and posterior sides for 50 seconds. The intervention was run through 9 sessions (One day in between). Patients received high power laser (4 watts) in the first session. In the other sessions low power laser (0.5 watts) was used.

**Main outcome variables**
Pain, joint clicks

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20180504039522N2**
Registration date: **2018-07-09, 1397/04/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-09, 1397/04/18**
Update count: **0**

**Registration date**
2018-07-09, 1397/04/18

**Registrant information**

**Name**
Ali Heidari

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 81 3838 0320

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ali.heidari68@umasha.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-06-22, 1397/04/01

**Expected recruitment end date**
2018-09-23, 1397/07/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effectiveness of intra-articular Triamcinolone injection compared to 940nm diod laser therapy in the treatment of temporomandibular joint disorder (TMD) signs.

**Public title**
The Effect of Triamcinolone Injection and Diode Laser on Improving the Symptoms of Temporomandibular Joint Disorders
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients with symptoms of TMD including pain, joint sound, limitation of mouth opening and jawbone deviation during mouth opening through clinical examinations
**Exclusion criteria:**
Age younger than 20 or older than 40 History of any surgery or intervention in the TMJ joint History of connective tissue or joints disease such as lupus, scleroderma, vasculitis, etc. History of long-term use of corticosteroids and anti-inflammatory drugs.
**Age**
From **20 years** old to **40 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **66**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Random allocation will be done through block randomization method.
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics committee of Hamadan University of Medical Sciences
**Street address**
Hamadan University of Medical Sciences, Shahid Fahmideh Blvd.
**City**
Hamadan
**Province**
Kohgilouyeh-va-Boyrahmad
**Postal code**
65156
**Approval date**
2018-01-13, 1396/10/23
**Ethics committee reference number**
IR.UMSHA.REC.1396.721

## Health conditions studied

**1**

**Description of health condition studied**
temporomandibular joint disorder (TMD)
**ICD-10 code**
M26.60
**ICD-10 code description**
Temporomandibular joint disorder, unspecified

## Primary outcomes

**1**

**Description**
Pain
**Timepoint**
Before treatment, one week later and one month later
**Method of measurement**
Visual Analog Scale(VAS)

**2**

**Description**
Joint klick
**Timepoint**
Before treatment, one week later and one month later
**Method of measurement**
Visual Analog Scale(VAS)

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group 1: Treatment included cleaning the skin of the injection area with alcoholic pad and injecting 1 ml of Lidocaine 2% to desensitize the area, asking the patient to open his mouth to the maximum possible size and injecting 0.5 ml of triamcinolone into posterior disk space. Needle gage 27was used for injection.
**Category**
Treatment - Drugs

**2**

**Description**
Intervention group 2: 940 nm diode laser was used to radiate point by point at the head of condyle from superior, inferior, anterior and posterior sides for 50 seconds. The intervention was run through 9 sessions (One day in between). Patients received high power laser (4 watts) in the first session. In the other sessions low power laser (0.5 watts) was used.

**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Oral and Maxillofacial Surgery medical centers in Hamedan

**Full name of responsible person**
Minoo Yavarikia

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Hamadan University of Medical Sciences, Shahid Fahmideh blvd

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Hamedan University of Medical Sciences

**Full name of responsible person**
Dr Saeed Bashirian

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Hamadan University of Medical Sciences, Shahid Fahmideh blvd

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saeedBashirian@yahoo.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Hamedan University of Medical Sciences

**Proportion provided by this source**
100

**Public or private sector**
Public

**Domestic or foreign origin**
Domestic

**Category of foreign source of funding**
*empty*

**Country of origin**

**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Hamedan University of Medical Sciences

**Full name of responsible person**
Dr Ali Heidari

**Position**
Assistant Professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Dentistry

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## Person responsible for scientific inquiries

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Dr Ali Heidari

**Position**
Assistant Professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Dentistry

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## Person responsible for updating data

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Dr Ali Heidari
**Position**
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**Latest degree**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
No more information
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available
**Title and more details about the data/document**
Only part of the original outcome information or the like can be shared.
**When the data will become available and for how long**
From the April first, 2019
**To whom data/document is available**
Data will be available for researchers working in academic and scientific institutions or industry professionals.
**Under which criteria data/document could be used**
Only published results from the Thesis can be used
**From where data/document is obtainable**
Dr ali Heidari dr-heidari68@hotmail.com
**What processes are involved for a request to access data/document**
Send an email to dr-heidari68@hotmail.com and get up to 72 hours to receive the response
**Comments**